

# **STABILITY ANALYSIS OF ISS MEDICATIONS**

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## **INTRODUCTION**

It is known that medications degrade over time, and that extreme storage conditions will hasten their degradation. The temperature and humidity conditions of the ISS have been shown to be within the ideal ranges for medication storage, but the effects of other environmental factors, like elevated exposure to radiation, have not yet been evaluated. Current operational procedures ensure that ISS medications are re-stocked before expiration, but this may not be possible on long duration exploration missions. For this reason, medications that have experienced long duration storage on the ISS were returned to JSC for analysis to determine any unusual effects of aging in the low-Earth orbit environment.

## **METHODS**

Medications were obtained by the JSC Pharmacy from commercial distributors and were re-packaged by JSC pharmacists to conserve up mass and volume. All medication doses were part of the ISS crew medical kit and were transported to the International Space Station (ISS) via NASA's Shuttle Transportation System (Space Shuttle). After 568 days of storage, the medications were removed from the supply chain and returned to Earth on a Dragon (SpaceX) capsule. Upon return to Earth, medications were transferred to temperature and humidity controlled environmental chambers until analysis.

Nine medications were chosen on the basis of their availability for study. The medications included several of the most heavily used by US crewmembers: 2 sleep aids, 2 antihistamines/decongestants, 3 pain relievers, an antidiarrheal and an alertness medication. Each medication was available at a single time point; analysis of the same medication at multiple time points was not possible. Because the samples examined in this study were obtained opportunistically from medical supplies, there were no control samples available (i.e. samples aged for a similar period of time on the ground); a significant limitation of this study. Medications were analyzed using the HPLC/MS methods described in the United States Pharmacopeia (USP) to measure the amount of intact active ingredient, identify degradation products and measure their amounts. Some analyses were conducted by an independent analytical laboratory, but certain (Schedule) medications could not be shipped to their facility and were analyzed at JSC.

## **RESULTS**

Nine medications were analyzed with respect to active pharmaceutical ingredient (API) and degradant amounts. Results were compared to the USP requirements for API and degradants/impurities content for every FDA-approved medication. One medication met USP requirements at 5 months after its expiration date. Four of the nine (44% of those tested) medications tested met USP requirements up to 8 months post-expiration. Another 3 medications (33% of those tested) met USP guidelines 2-3 months before expiration. One medication, a compound classed by the FDA as a dietary supplement and sometimes used as a sleep aid, failed to meet USP requirements at 11 months post-expiration.

## **CONCLUSION**

Analysis of each medication at a single time point provides limited information on the stability of a medication stored in particular conditions; it is not possible to predict how long a medication may be safe and effective from these data. Notwithstanding, five of the nine medications tested (56%) met USP requirements for API and degradants/impurities at least 5 months past expiration dates. The single compound that failed to meet USP requirements is not regulated as strictly as prescription medications are during manufacture; it is unknown if this medication would have met the requirements prior to flight. Notably, it was the furthest beyond its expiration date. Only more comprehensive analysis of flight-aged samples compared to appropriate ground controls will permit determination of spaceflight effects on medication stability.